Chapter 2

The Risk Assessment Process for the Part 503 Biosolids Rule

The biosolids risk assessment process involved selecting representative pathways by which humans, animals, and plants could become exposed to pollutants of concern that can be present in biosolids. Data on exposures associated with each pathway were combined with data on allowable doses of a pollutant to develop a limit for that pollutant. The process by which pollutants of concern and appropriate exposure pathways were selected, as well as the key scientific analyses, deliberations, and policy decisions involved in the biosolids risk assessment process, are summarized in Table 1 and outlined in Figure 2. The large letters to the left of each section heading in the text indicate when in the risk assessment process the step occurred. These letters also are shown in Table 1 (this chapter) and throughout Chapter 3.

Initial List of Pollutants

Step A Biosolids Task Force Study

The biosolids risk assessment process began in 1982 when the Intra-Agency Biosolids Task Force was established to assess biosolids management approaches nationwide, evaluate existing regulatory activities, and identify data needs. In 1983 the task force recommended that a comprehensive regulatory program be developed by EPA under the authority of Section 405 of the Clean Water Act and other environmental statutes. The Agency identified several key components for such a program, including:

- Determining pollutants of concern
- Developing risk assessment methodologies
- Determining appropriate risk-based pollutant limits and management practices
- Issuing comprehensive, risk-based regulations (i.e., the Part 503 rule)

Table 1

The Biosolids Risk Assessment and Rule Development Process

Developmental Step	Mechanism Used	Key Features
Step A Intra-Agency Sludge (Biosolids) Task Force Study	Team within EPA worked directly under the Assistant Administrators to develop a biosolids management and regulatory plan	The Task Force worked intensively to develop a comprehensive plan with input from all impacted groups
Step B Identification of 200 pollutants	EPA list	Pollutants placed on list based on expected toxicity
Step C Selection of 50 pollutants from 200 for further study	Four panels of experts met to recommend pollutants for land application (LA), surface disposal (SD), incineration (I), and ocean disposal (OD) of biosolids	Selection based on best professional judgment: likelihood that environmental and human exposure will occur via LA, SD, I, or OD; known pollutant toxicity via relevant exposure pathways; and availability of exposure and toxicity data
Step D Initial identification of exposure pathways for each use or disposal practice	Expert panels identified appropriate exposure pathways for each pollutant	Selection based on best professional judgment
Step E Profile assessment and hazard indices developed for 50 pollutants	Hazard indices developed with the assistance of a contractor	Profile assessment and hazard indices based on: —pollutant toxicity —pollutant concentration in soil, water, air, food, and/or biosolids —worst-case data —extreme exposure for most exposed individual (MEI)
Step F Selection of pollutants for detailed risk assessment	Environmental profiles developed based on results of hazard indices	If hazard indices were 1 or greater, pollutants were considered for detailed risk assessment and regulation
Step G Risk assessment methodology review	Review by EPA Science Advisory Board (SAB)	Reviewed algorithms, exposure routes, assumptions
Step H Risk assessments for LA, SD, I, OD for proposed Part 503 rule	EPA with contractor assistance	—MEI —conservative models and assumptions —worst-case data—e.g., salt data for plant uptake, use of 98th percentile for non-agricultural (ag) LA
Step I Published proposed Part 503 rule for comment	Published in the *Federal Register*, February 6, 1989, for public comment and external review	5,500 pages of comments received; LA and SD peer review; incineration review by SAB
Step J Risk assessments for final Part 503 rule revised based on comments; expert advisors continue reviews	EPA/advisors met to review and modify data selection, models used, data management	—changed from MEI to highly exposed individual (HEI) —changed models —used field data —developed data management protocol —combined distributed-and-marketed, ag, and non-ag LA data

(Continued)

Table 1 (Continued)

Developmental Step	Mechanism Used	Key Features
Step K National Sewage Sludge Survey (NSSS)	$1.2 million study involving biosolids sample collection and analyses, and questionnaire	Statistically based groups of publicly owned treatment works (POTWs) (totaling 180) for biosolids sampling and analysis, and additional information from 475 POTWs for data on use and disposal practices, costs, impacts of the proposed rule, etc. Information used to evaluate: —current pollutant concentrations in biosolids (412 analytes) —current biosolids use or disposal practices —impact of rule on current practices
Step L Published NSSS results and proposed changes for final Part 503 rule for comment	Published in the *Federal Register*, November 9, 1990, for public comment and external review	Comments received from 153 respondents; Proposed alternate pollutant limit concept for "clean" biosolids
Step M Revised risk assessments for final Part 503 rule	EPA with assistance of team of experts and contractor	Areas of change included: —protecting HEI rather than MEI —greater emphasis on field study data —refined models, data, assumptions —use of NSSS results —revised pathways
Step N Internal EPA review of draft final Part 503 rule	All EPA offices reviewed rule and identified issues of concern	Major issues identified: —biosolids binding —phytotoxicity —concerns about ecological risk —nitrogen management issues Major risk management decisions: —use of 99th percentile concentrations from NSSS —use of agronomic rate for nitrogen —"clean" biosolids emphasis
Step O Published final Part 503 rule	Published final rule in *Federal Register*, February 19, 1993	40 CFR Part 503 with subparts on: general provisions, land application, surface disposal, pathogens and vector attraction reduction, and incineration
Step P Amendment to rule to address lawsuits and EPA revisions to the final Part 503 rule	Published in *Federal Register*, February 24, 1994	Issues: —land application: molybdenum, cadmium, chromium pollutant limits; annual pollutant loading rates (APLR); selenium —incineration: THC vs. carbon monoxide (CO) monitoring Amendments for: certain molybdenum pollutant limits for land application; THC/CO—continuous emission monitoring

(Continued)

Table 1 (Continued)

Developmental Step	Mechanism Used	Key Features
Step Q Rulings on court cases	Remanded portions of the Part 503 rule for modification or further justification; issues included: —land application chromium limits —99th-percentile land application limit for chromium and selenium —special land application limits for heat-dried biosolids —special selenium limits for land application on public contact sites with a low potential for occupancy	Undergoing review by EPA as of August 10, 1995

Step B Identification of 200 Pollutants

The process of identifying pollutants of concern began in 1984, when EPA developed for possible consideration a list of approximately 200 pollutants based on the following types of available data:

- Human exposure and health effects
- Plant uptake of pollutants
- Phytotoxicity (adverse effects on plants)
- Effects in domestic animals and wildlife
- Effects in aquatic organisms
- Frequency of pollutant occurrence in biosolids

Step C Selection of Pollutants by Scientific Experts for Further Consideration From the List of 200 Pollutants

In 1984 the Agency submitted its initial list of 200 pollutants for review by four panels of experts covering land application, surface disposal, incineration, and ocean disposal of biosolids. The panels recommended that approximately 50 of the 200 pollutants listed be studied further. The recommended list of pollutants was based on:

- The probability that the pollutant would be toxic when exposure occurred through use or disposal of biosolids.
- The likelihood that human and environmental exposure to the pollutant would occur via land application, surface disposal, incineration, or ocean disposal of biosolids.
- The availability of toxicity and exposure data for the pollutants.
- Best professional judgment.

Figure 2
Steps in the Development of the Part 503 Risk Assessment and Rule

1982	EPA establishes Intra-Agency Sludge (Biosolids) Task Force
1982	EPA publishes results of the "40 Cities Study"
1983	EPA Biosolids Task Force presents recommendations, including need for comprehensive regulatory program
March 1984	EPA develops list of 200 pollutants
May 1984	Experts select 50 pollutants for further study and identify exposure pathways
1984-85	EPA conducts worst-case hazard profile assessment
1985	Science Advisory Board approves general risk assessment methodology, including algorithms, exposure routes, and assumptions, but does not check data selection
1986-88	EPA conducts risk assessments protecting MEI, using worst-case data, assumptions, and models
1988	The ocean dumping option is dropped from the rule due to the Ocean Disposal Ban Act of 1988
Feb. 1989	EPA publishes proposed Part 503 rule for comment
July 1989	Peer review of Part 503 is conducted; report points out scientific reasons why pollutant limits in proposed rule are overly stringent and recommends that more realistic limits be developed
1988-89	EPA conducts National Sewage Sludge Survey (NSSS)
Jan. 1990	A team of experts is established to assist EPA with revision of rule
1990	EPA selects new data, assumptions, and models to use in revising risk assessments
Nov. 1990	EPA publishes NSSS results and possible changes to the proposed rule for public comment
1990-92	EPA conducts revised risk assessments protecting HEI, using field data, and modified assumptions and models; incorporates comments in NSSS notice
1992	Internal Agency-wide review of Part 503 rule by EPA completed
Nov. 1992	Administrator approves final Part 503 rule
Feb. 1993	EPA publishes final Part 503 rule and notices of availability of supporting documents
Feb. 1994	EPA publishes an amendment to Part 503 rule
1993-95	EPA identifies 32 additional biosolids pollutants for regulatory consideration by year 2000. Further analysis may narrow the focus for consideration primarily to dioxins, furans, and PCBs
1994-95	EPA considers 4 provisions of Part 503 rule remanded by court for modification or additional justification
1994-95	EPA begins ecological and field monitoring studies on specific issues identified for additional investigation during development of Part 503 rule
Nov. 1995	Additional ("Round 2") list of biosolids pollutants developed for regulatory consideration by the year 2000
Dec. 1999	Proposed "Round 2" amended regulation
Dec. 2001	Final "Round 2" amended regulation

Hazard Profiles of the 50 Pollutants Selected for Further Evaluation

Step D Initial Identification of Exposure Pathways for Hazard Assessment

A preliminary exposure assessment was conducted to develop "environmental profiles" for each of the 50 pollutants. The exposure assessments were based on "pathways" by which an individual (person, animal, or plant) could be exposed to a pollutant in biosolids. To determine appropriate exposure pathways, EPA adapted existing exposure models and developed new ones to represent the movement of pollutants in the environment and ultimately to an affected individual. Identification by experts of the exposure pathways for each use and disposal practice began in 1984 (conducted by a group that included the same experts that recommended further evaluation of 50 pollutants, see above). The exposure assessment was subsequently used to develop the risk assessments conducted for both the proposed and the final biosolids rule.

Step E Profile Assessments of 50 Pollutants

The environmental profile developed for each of the 50 pollutants included a compilation of data on toxicity, occurrence, and fate and effects of the pollutant. Information on occurrence (i.e., frequency and concentration of pollutants in biosolids) was obtained from the "40 Cities Study" (described below), which was considered the best source for such data at the time. Each environmental profile also evaluated hazards of pollutants associated with particular exposure pathways. Not all pollutants were evaluated for each pathway because some pathways were considered unlikely routes of exposure for certain pollutants.

Using a **hazard index** (Box 2), the environmental profiles evaluated the hazards for each of the 50 pollutants in biosolids by comparing a pollutant's concentration in the environment (in soil, plant or animal tissue, water, or air) with established human health and other regulatory criteria (e.g., acceptable daily intake for a noncarcinogen, or a cancer risk-specific intake). EPA assumed worst-case conditions in this initial assessment (i.e., maximum exposure of an individual to a pollutant in its most bioavailable form via the most sensitive route of exposure, assuming maximum toxic effect).

Step F Use of the Hazard Profile Process To Select Pollutants for Detailed Risk Assessment

Selection of pollutants for detailed risk assessment using the hazard indices evaluation involved a two-part process (EPA, 1985). First, all sources of exposure to a pollutant was considered, including biosolids and background levels of a pollutant from sources other than biosolids. A hazard index of less than 1 indicated that the concentration in the environment was lower than the concentration known to be toxic to the organism being evaluated. It also indicated that the pollutant was not a hazard to humans, animals, or plants via the pathway being evaluated, even when factoring in exposures to background concentrations of the pollutant in soil, water, air, and plants. Pollutant/pathway combinations with hazard indices of less than 1 were dropped from further consideration.

A hazard index value of 1 or greater indicated that a pollutant was potentially toxic. Each pollutant in this higher-value group was then further evaluated in the second part of the process, called **hazard ranking**, by adjusting the index so that it

Box 2
Calculation and Use of Hazard Index and Hazard Ranking for Biosolids

Hazard Index:

$$Pollutant\ hazard\ index = \frac{Estimated\ concentration\ in\ soil,\ plant\ or\ animal\ tissue,\ water,\ or\ air}{Lowest\ concentration\ toxic\ to\ organism\ being\ evaluated}$$

1. The hazard index for pollutants in biosolids was calculated by comparing:
   a.) the estimated concentration of the pollutant in soil, plant or animal tissue, ground water, surface water, or air (based on the "40 Cities Study" data on pollutant concentrations in biosolids and on pollutant transport and fate data) to:
   b.) the lowest concentration of a pollutant shown to be toxic to the organism being evaluated (as indicated by available scientific data) via the most sensitive route of exposure (i.e., ingestion, inhalation, or injection) while assuming maximum toxic effect.
2. Pollutants with hazard index values of less than 1 for "worst-case" conditions via certain pathways were not analyzed further for that pathway because a value of less than 1 indicated that the pollutant was not toxic to the organism. For example:

Lindane (Soil Biota Predator Toxicity):

$$Index = \frac{I_1 x\ UB}{TR} = \frac{0.129950 x 1.05}{50} = 0.002728$$

where: I_1 = Concentration of pollutant in biosolids-amended soil (µg/g dry weight [DW])
UB = Uptake factor of pollutant in soil biota (µg pollutant/g tissue DW [µg pollutant/g soil DW]$^{-1}$)
TR = Feed concentration toxic to predator (µg pollutant/g tissue DW)

3. Pollutants with hazard index values of 1 or greater for certain pathways were considered to be potentially toxic and were further evaluated (unless the circumstances did not warrant further study, predominantly because the data were insufficient). For example:

Lindane (Human Cancer Risk Resulting from Soil Ingestion [toddler]):

$$Index = \frac{(I_1 x\ DS) + DI}{RSI} = \frac{0.129950 + 2.71}{0.053} = 63.39152$$

where: I_1 = Concentration of pollutant in sludge-amended soil (µg/g DW)
DS = Assumed amount of soil in human diet (g/day)
DI = Average daily human dietary intake of pollutant (ug/day)
RSI = Cancer risk-specific intake (ug/day)
DW = Dry weight

Hazard Ranking:

4. Pollutants with hazard index values of 1 or greater were then evaluated to determine what portion of the hazard associated with a pollutant was attributable to its presence in biosolids. After adjustment (i.e., subtraction of background values so that pollutant exposure from sources other than biosolids were excluded from the rankings), indices for each of the pollutants were ranked (i.e., less than 1; 1 to 100; 100 to 1,000; and greater than 1,000). Higher rankings indicated greater potential risk from pollutants in biosolids. Ultimately, all hazard index rankings of 1 or greater received addditional evaluation. (Note: Background pollutant concentrations were considered in the exposure calculations for organisms during the risk assessments for both the proposed and the final Part 503 rule.)
5. If the portion of a pollutant's hazard attributable to biosolids resulted in a hazard ranking of less than 1, the pollutant was not analyzed further.
6. Pollutants with hazard rankings of greater than 1 were evaluated in the risk asessments conducted for biosolids use or disposal practices, with the exception of fluoride, iron, and pollutants deferred due to insifficient data (see text).

reflected only the pollutant's hazard attributable to biosolids. This adjustment was made by excluding background exposures to the pollutant from sources other than biosolids. The remaining value indicated impacts from pollutants in biosolids only.

The adjusted hazard indices then were ranked into one of the four hazard ranking groups—ranging from less than 1, 1 to 100, 100 to 1,000, and greater than 1,000—for the purpose of evaluating those pollutant indices with the highest score first. The weighted scores, however, were not used. Instead, all pollutant/pathway combinations with hazard rankings of 1 or more were evaluated in more detail (as discussed below and in Box 2), while pollutant/pathway combinations with indices of less than 1 were eliminated from further consideration.

All pollutant/pathway combinations assigned a hazard ranking of 1 or greater in the environmental profile process were selected for evaluation in the detailed risk assessments for biosolids, with the exception of fluoride and iron (discussed in Chapter 3) and pollutants for which further evaluation was deferred because of insufficient data. This process resulted in narrowing the list of pollutants to 22 for assessing risks from land application of biosolids, 16 for surface disposal, and 14 for incineration (see Table 2). Several additional pollutants were added or deleted from further analysis, as indicated in Table 3.

Some pollutants were not evaluated for all use or disposal practices (i.e., land application, surface disposal, incineration) because different practices may result in different routes of exposure and different potential risks from the same pollutant. For example, a pollutant might be toxic if a person inhales it from the air near a biosolids incinerator, but not be toxic if consumed in a crop grown on soil where biosolids were used as a fertilizer.

Risk Assessments Conducted for the Proposed Part 503 Rule

Step G EPA Science Advisory Board Review of Risk Assessment Methodology for the Proposed Rule

The methodologies used for the risk assessments conducted as a basis for the Part 503 proposed rule were reviewed and approved by EPA's Science Advisory Board (SAB). It is important to note that the review of the risk assessment methodologies by the SAB did not include the data used for the ***algorithms*** because this information was not available at that time. Algorithms are mathematical equations used in a risk assessment model to relate various relevant parameters (e.g., of exposure and dose response) for pollutants in applicable pathways. For the biosolids risk assessments, the algorithms ultimately were used to identify pollutant limits. Algorithms are discussed in detail in Chapter 4.

Step H Risk Assessments for Proposed Part 503 Pollutant Limits

Based on the SAB's favorable review of the risk assessment methodologies, EPA conducted separate risk assessments for land application, monofilling, and incineration of biosolids using toxicity and exposure data available at that time. Although a risk assessment methodology for ocean disposal of biosolids was developed and reviewed by the SAB, a risk assessment for this biosolids disposal practice was not conducted once the Ocean Disposal Ban Act of 1988 prohibited this disposal practice.

EPA conducted the initial biosolids risk assessments using highly conservative assumptions and worst-case exposure data in an attempt to ensure protection of public health and the environment. The conservative approach was adopted

because a court-ordered schedule limited the time available to conduct the risk assessments and then develop the rule.

Factors of Importance in the Risk Assessments for the Proposed Part 503 Rule: Some of the key factors and conservative assumptions and approaches used in the biosolids risk assessments conducted for the proposed Part 503 rule are presented below. Many of these factors were the subject of lengthy scientific and policy deliberations (as discussed in Chapter 3) and, subsequently, were reevaluated and revised in the risk assessments conducted for the final Part 503 rule (as discussed later in this chapter). The key factors in the risk assessments for the proposed Part 503 rule included:

- ***How Organisms Are Exposed:*** Different exposure pathways (the ways in which people, animals, and plants can become exposed to pollutants in biosolids) were evaluated for agricultural land application, non-agricultural land application (i.e., forests and reclamation sites), distribution and marketing, surface disposal, and incineration of biosolids. All use or disposal practices except for non-agricultural land application and surface disposal (monofills) were evaluated by formal scientific exposure assessments (use of algorithms). (Much of the data, assumptions, models, and endpoints used in the risk assessments for the proposed rule were refined or changed for the final Part 503 risk assessments.)
- ***98th-Percentile Approach:*** A 98th-percentile (policy-based) approach was used by EPA to develop pollutant limits for biosolids applied to non-agricultural land and placed on a surface disposal site. The 98th-percentile pollutant concentrations were calculated based on data from the "40 Cities Study" and were used as "ceilings" for allowable pollutant concentrations in biosolids for the proposed regulation. (Changed to the 99th-percentile for the final rule risk assessments.)
- ***Who Is at Risk:*** Two types of risk were chosen for evaluation—individual and aggregate risks:
  - ***Individual risks*** were evaluated for the "most exposed individual" (MEI) for each pollutant and pathway. For humans, this MEI was the most sensitive individual being continuously exposed over a 70-year lifetime to a pollutant at its maximum concentration in a given pathway. For plants and animals, the MEI was the most exposed or most sensitive species exposed over its critical life period to the maximum pollutant solubility, bioavailability, and/or concentration. (Changed to the highly exposed individual [HEI] for the final rule risk assessments.)
  - ***An aggregate risk assessment*** was conducted to determine the benefits of the regulation in terms of numbers of cancer cases avoided in the population nationally, as required in the Regulatory Impact Analysis for the Part 503 rule. The aggregate risk assessment multiplied the risks to individuals (as described above) by the estimated number of individuals exposed to determine the number of cases avoided. The aggregate risk assessment was not used as a basis for determining pollutant limits or management practices in the final Part 503 rule.
- ***Quantifying Health Effects:*** Conservative criteria, such as risk reference doses (RfDs) and cancer potency values (q_1^*s), among others, were used in algorithms for calculating pollutant exposure limits (see Box 3). (Retained for the final rule risk assessments.)

Table 2

Pollutants Remaining After Hazard Index, Hazard Ranking, or Deferral

Pollutants Evaluated	Land Application[a]			Surface Disposal[b]			Incineration		
	Hazard Index	Hazard Ranking[c]	Deferral (yes = not deferred)[d]	Hazard Index	Hazard Ranking	Deferral (yes = not deferred)	Hazard Index	Hazard Ranking	Deferral (yes = not deferred)
Aldrin/Dieldrin	yes	yes	yes	—[e]	—	—	yes	yes	yes
Arsenic	yes	yes	yes	yes	no	NA[f]	yes	yes	yes
Benzene	—	—	—	yes	yes	yes	yes	no	NA
Benzo(a)anthracene	no	no	deferred	—	—	—	yes	no	deferred
Benzo(a)pyrene	yes	yes	yes	yes	yes	yes	yes	yes	yes
Bis(2-ethylhexyl) phthalate	yes	no	deferred	yes	yes	yes	yes	yes	yes
Beryllium	—	—	—	—	—	—	yes	yes	yes
Cadmium	yes	yes	yes	yes	no	NA	yes	yes	yes
Carbon tetrachloride	—	—	—	—	—	—	yes	yes	yes
Chlordane	yes	yes	yes	yes	yes	yes	yes	yes	yes
Chloroform	—	—	—	—	—	—	yes	yes	yes
Chromium	yes	yes	yes	yes	no	NA	yes	yes	yes
Cobalt	yes	no	deferred	yes	no	deferred	—	—	—
Copper	yes	yes	yes	yes	yes	yes	—	—	—
Cyanide	no	no	NA	yes	yes	yes	no	no	NA
DDT/DDE/DDD	yes	yes	yes	yes	yes	yes	yes	no	NA
2,4-Dichloro-phenoxyacetic acid	—	—	—	yes	no	NA	no	no	NA
Dioxins	—	—	deferred	—	—	deferred	no	no	deferred
Fluoride	yes	yes	yes	—	—	—	—	—	—
Furans	—	—	deferred	—	—	deferred	no	no	deferred
Heptachlor	yes	yes	yes	—	—	—	yes	no	NA
Hexachlorobenzene	yes	yes	yes	—	—	—	—	—	—
Hexachlorobutadiene	yes	yes	—	—	—	—	—	—	—
Iron	yes	yes	yes	—	—	—	—	—	—
Lead	yes	yes	yes	yes	yes	yes	yes	yes	yes
Lindane	yes	yes	yes	yes	yes	yes	yes	no	NA
Malathion	—	—	—	yes	no	NA	no	no	NA
Mercury	yes	yes	yes	yes	yes	yes	yes	no	NA
Methyl ethyl ketone	—	—	—	no	no	deferred	—	—	—
Methylenebis(2-chloro-) aniline	yes	no	deferred	—	—	—	—	—	—
Methylene chloride		no	deferred	yes	no	deferred	yes	no	NA
Molybdenum	yes	yes	yes	yes	no	no	—	—	—

(Continued)

Table 2 (Continued)

Pollutants Evaluated	Land Application[a]			Surface Disposal[b]			Incineration		
	Hazard Index	Hazard Ranking[c]	Deferral (yes = not deferred)[d]	Hazard Index	Hazard Ranking	Deferral (yes = not deferred)	Hazard Index	Hazard Ranking	Deferral (yes = not deferred)
Nickel	yes	yes	yes	yes	yes	yes	yes	yes	yes
n-Nitroso-dimethylamine[g]	yes	no	NA	yes	yes	yes	—	—	—
Polychlorinated biphenyls (PCBs)	yes	yes	yes	yes	yes	yes	yes	yes	yes
Pentachlorophenol	yes	no	deferred	—	—	—	no	no	NA
Phenanthrene	—	—	—	yes	no	deferred	yes	no	deferred
Phenol	—	—	—	—	—	—	no	no	NA
Selenium	yes	yes	yes	—	—	—	—	—	—
Tetrachloroethylene	—	—	—	—	—	—	yes	no	NA
Toxaphene	yes	yes	yes	yes	yes	yes	yes	yes	yes
Trichloroethylene	no	no	NA	—	—	—	no	no	NA
Tricresyl phosphate	yes	no	deferred	—	—	—	—	—	—
Vinyl chloride	no	no	NA	no	no	NA	yes	no	deferred
Zinc	yes	yes	yes	yes	no	NA	yes	no	NA

[a]Includes land application and distribution and marketing; for later risk assessment, these two categories were combined.

[b]Surface disposal was evaluated as "Landfilling" in the Hazard Index/Ranking.

[c]Pollutants remaining after the hazard ranking had a hazard index/ranking ≥1 and were included in the Part 503 risk assessment. Pollutants with a hazard index/ranking of <1 were excluded from further analysis, except as discussed in Table 3.

[d]Some pollutants were deferred after the hazard index/hazard ranking process due to lack of data; pollutants marked "yes" remained for further analysis.

[e]— = not evaluated for that use or disposal practice.

[f]NA = deferral not applicable because hazard ranking indicated that pollutant did not pose a hazard (for exceptions, see Table 3).

[g]Also known as dimethyl nitrosamine.

- ***Acceptable Level of Cancer Risk From Potentially Toxic Organic Pollutants:*** Risks at 1×10^{-4} (1 case of cancer in a population of 10,000), 1×10^{-5} (1 case in 100,000), and 1×10^{-6} (1 case in 1,000,000) were evaluated. For the proposed Part 503 regulation, EPA made a policy decision to regulate risk at 1×10^{-4} for land application and surface disposal and at 1×10^{-5} for incineration. (The cancer risk level for incineration was changed to 1×10^{-4} for the final rule risk assessments.)
- ***Type of Data Used:*** Worst-case plant uptake data were used in the risk assessments for the proposed rule. The worst-case data came predominantly from greenhouse pot studies and studies using metal salts. The use of data from biosolids field studies was limited. (This was changed to the use of predominantly field study data for the final rule risk assessments.)
- ***Linearity Assumption for Plant Uptake of Inorganic Pollutants:*** EPA used the conservative assumption that plant uptake of inorganic pollutants is linear (i.e., that crops take up a pollutant in a manner that is directly proportional to the amount of pollutant in biosolids applied to land). (Retained for the final rule risk assessments.)

Table 3

Pollutants Added or Deleted From Evaluation After Hazard Index/Ranking Completed

Pollutant	Added or Deleted	Reason
Benzene	Added for: land application	Evaluated with additional exposure pathways
	incineration	Regulated as total hydrocarbon (THC) operational standard
Bis(2-ethylhexyl) phthalate	Added for land application	Evaluated with additional exposure pathways
Cadmium	Added for surface disposal	Additional data available, and for consistency with land application risk assessment
Chromium	Added for surface disposal	Additional data available, and for consistency with land application risk assessment
DDT/DDE/DDD	Added for incineration	Regulated as THC operational standard
Dioxins	Added for incineration	Regulated as THC operational standard
Fluoride	Deleted for land application	Limited data indicating toxicity
Furans	Added for incineration	Regulated as THC operational standard
Heptachlor	Added for incineration	Regulated as THC operational standard
Iron	Deleted for land application	Limited data indicating toxicity
Lindane	Added for incineration	Regulated as THC operational standard
Mercury	Added for incineration	Regulated through NESHAPS[a] standard
n-Nitroso-dimethylamine	Added for land application	Evaluated with additional exposure pathways
Trichloroethylene	Added for land application	Evaluated with additional exposure pathways

[a]NESHAPS = National Emissions Standards for Hazardous Air Pollutants

- ***Food Consumption:*** EPA used conservative dietary data to determine human exposure to pollutants in biosolids through food consumption. The risk assessment used the highest daily consumption rate of each of eight food groups (e.g., consumption of dairy products by the teen-age male) to calculate risk to humans from consuming plant or animal products grown or raised on soils to which biosolids were applied. (Refined for the final rule risk assessments.)
- ***Pollutant Transport:*** Particularly conservative models were used for predicting pollutant transport into ground water, surface water, and air. (Refined for the final rule risk assessments.)
- ***Organic and Inorganic Pollutants:*** Potential risks from both organic and inorganic pollutants were assessed. (Retained for the final rule risk assessments.)
- ***The "40 Cities Study":*** During the initial risk assessment process, the primary source of information on the presence and concentration of pollutants in biosolids evaluated in the risk assessments for the proposed Part 503 rule was the "40 Cities Study," published in 1982 (U.S. EPA, 1982). This study did not reflect the quality of biosolids used or disposed at the time of the proposed rule (1989) because:
  - The study included primarily data on biosolids in various stages of treatment at publicly owned treatment works (POTWs) prior to final processing, rather than data on final, processed biosolids leaving POTWs that were used or disposed.

Box 3
Quantifying Cancer and Noncancer Effects: Q_1*s and RfDs

For many analyses conducted for the biosolids risk assessments, EPA used cancer potency values (q_1*s) or risk reference doses/concentrations (RfDs/RfCs) to measure toxic human effects, as described below. Both q_1*s and RfDs/RfCs are conservative measures because they predict greater impacts on human health than are likely to actually occur and because both values assume exposure for an entire lifetime (70 years). Q_1*s or RfDs were used in the biosolids risk assessments to calculate the concentration of pollutant in biosolids that is reasonably protective against adverse impacts.

*Cancer Effects: Q_1*s*

Cancer potency values (q_1*s) were used to quantify human cancer in the risk assessments for biosolids. A q_1* represents the dose at which an exposed individual would be expected to get cancer (i.e., the relationship between a specific dose of a carcinogenic [cancer-causing] substance and its associated degree of risk). The degree of risk (i.e., 1×10^{-4}) is a policy decision made by the Agency that indicates an acceptable degree of cancer risk for the most exposed person, based on that person's continual exposure at that dose for a lifetime (e.g., 70 years). In evaluating cancer risks, EPA conservatively assumes that any exposure to a carcinogen produces a measurable risk. The q_1* is a "bounding" (upper-limit) estimate; the true risk to humans is not likely to exceed the q_1*, and probably is lower. Q_1*s are based on data for the most sensitive animal as well as on conservative (i.e., linear) extrapolation from high doses (used in laboratory experiments) to low doses (representative of actual human exposure). Q_1*s for specific pollutants are listed in EPA's computerized Integrated Risk Information System (IRIS) data base, which can be accessed through the National Library of Medicine.

Noncancer Risks: RfDs/RfCs

Reference dose (RfD) or ***reference concentration (RfC)*** values were used in the biosolids risk assessments to indicate health effects other than cancer from exposure to inorganic pollutants in biosolids. RfDs/RfCs are conservative estimates of the amount of a chemical that can be consumed daily without appreciable risk of ill effects during a lifetime. Thus, these values identify "thresholds" for noncancer health effects; no such threshold was identified for cancer risks discussed above because any dose of a carcinogen is assumed to be capable of producing a carcinogenic effect. Conservative safety factors ranging from 10 to 10,000 are incorporated into RfDs/RfCs to address areas of uncertainty, such as extrapolation from short-term to long-term exposure, interspecies sensitivity, and variation in sensitivity in humans. Like q_1*s, RfDs/RfCs are listed in EPA's IRIS data base. The Clean Water Act requires that EPA protect against reasonably anticipated adverse effects of each regulated pollutant in biosolids. For example, the chosen RfD for cadmium protects against renal tubular proteinuria.

- The study was designed to trace the fate of toxics in POTWs that had received significant volumes of industrial wastewater discharge (and thus potentially high concentrations of pollutants in resulting biosolids).
- Many POTWs have initiated pretreatment programs since 1978, resulting in cleaner biosolids.
- Wastewater treatment processes have changed over time.
- Advances in analytical procedures since the "40 Cities Study" allow for more accurate analyses of pollutants in biosolids.

Realizing the limitations of the "40 City Study," EPA conducted a much more representative evaluation of biosolids from POTWs across the United States (and pollutants in those biosolids) via a National Sewage Sludge Survey (NSSS). (NSSS data were used to help develop the final rule.)

Based on the results of the initial risk assessments and numerous policy decisions described above, EPA developed and published the proposed Part 503 rule for public comment in the February 6, 1989, issue of the *Federal Register*.

Comments on the Proposed Part 503 Rule and EPA's Response

Step I Public Review and Comment on the Proposed Part 503 Rule

EPA proposed the Part 503 rule on February 6, 1989 (54 FR 5746), seeking comment and additional data for improving the rule. Many different types of reviews were undertaken that resulted in more than 5,500 pages of comments received by the Agency. Some of the most extensive comments were received from expert peer review groups established by the Agency that included representatives from academia; federal, state, and local government agencies and research centers; and environmental organizations.

One of the expert peer review groups was organized by the U.S. Department of Agriculture's (USDA's) Cooperative State Research Service Technical Committee W-170 to assess the technical basis of the proposed rule for land application, distribution and marketing, monofilling, and surface disposal. This review group, called the Peer Review Committee (PRC), identified a number of deficiencies and recommended changes in the data, assumptions, and models used for the risk assessments. The PRC recommendations (USDA/CSRS, 1989) are listed in Table 4.

A second expert peer review group was assembled by the SAB to review the technical basis for the proposed incineration rule. This group's recommendations and findings (U.S. EPA, 1989a) are listed in Table 5.

Step J EPA Analysis of Comments on the Proposed Rule and Revision of the Risk Assessments

EPA performed an extensive analysis of the comments received and undertook a series of actions in response to the comments. Perhaps one of EPA's most important actions was to assemble a team of experts (Appendix C) with extensive research and experience related to the issues raised by the PRC and a number of the other commentors.

The team of experts met a number of times over 3 years to provide EPA with recommendations for improving the risk assessments, including the data, models, and assumptions that should be used. The team helped assemble and tabulate the available relevant data, advised EPA on the proper use of these data, and helped revise the models and assumptions used in the risk assessments. The experts recommended a number of significant changes to the proposed Part 503 rule. These changes were announced along with the results of the NSSS, both of which are described in the following section. EPA has continued to benefit from the assistance provided by members of this team during internal review and promulgation of the final rule and in explaining the risk assessment process at numerous meetings both in the United States and abroad.

Step K The National Sewage Sludge Survey

EPA conducted the NSSS in 1988 and 1989 to obtain a current and reliable data base on biosolids quality and management that could be used to help develop the final Part 503 rule. The NSSS included an analysis of 412 analytes in samples of biosolids from 180 POTWs as well as analysis of questionnaire information on use or disposal practices from 475 POTWs with secondary or more advanced wastewater treatment. The resulting national estimates of pollutant concentrations in

biosolids, quantities of biosolids generated, and biosolids treatment, practices, and related costs permitted a more accurate assessment of the level of risk posed by current biosolids quality and use or disposal practices.

Step L Publication of the NSSS Results and Proposed Changes for the Final Part 503 Rule

Upon completion of its analysis of review comments on the proposed Part 503 rule and the NSSS findings, EPA considered making a number of changes to the Part 503 rule. These changes were published along with the results of the NSSS in the November 9, 1990, issue of the *Federal Register* (55 FR 47210-47283) and entitled *National Sewage Sludge Survey: Availability of Information and Data, and Anticipated Impacts on Proposed Regulations.* The NSSS results indicated that pollutants exist at relatively low levels in today's biosolids, and the proposed changes to the rule reflect these results. The findings in that publication are discussed in more detail below.

NSSS Results: The NSSS results were significantly different from previous estimates of pollutant concentrations in biosolids. Concentrations of heavy metals, including cadmium, chromium, lead, nickel, zinc, beryllium, and mercury, were found to be substantially lower than previous estimates. In particular, lead concentrations were found to be only about 40 percent as high as previously estimated. Concentrations of most chlorinated organic pollutants also were confirmed to be low. Problems with limits of detection in the NSSS were overcome for the most part via a statistical procedure called maximum likelihood estimation for multiple censored points.

Biosolids samples also were analyzed for polychlorinated biphenyl (PCB) congeners. No detectable levels of PCB congeners 1016, 1221, 1232, or 1242 were found in any of the 198 tested samples. The remaining congeners—PCB 1248, 1254, and 1260—were found to be above the minimum detectible level in about 10 percent of the biosolids samples.

The national estimates of pollutant concentrations from the NSSS are considered appropriate and essentially unbiased statistically (except for PCBs, which differ from other pollutants in that they do not show a log normal distribution). The estimates were found to be statistically sound for several reasons:

- The surveyed POTWs were selected from all POTWs with secondary treatment identified by the 1986 Needs Survey, the most complete listing available.
- The POTWs included in the NSSS were selected to equally represent each of four representative POTW size ranges.
- Analytical protocols used to measure the concentration of pollutants in NSSS samples were specifically adapted for the biosolids matrix.
- While the wide differences in percent solids in the different biosolids samples analyzed resulted in detection limit problems, the statistical method used to incorporate sample results that were below the detection limit (known as the maximum likelihood estimation for multiple censored points technique) reduced the bias associated with more commonly used estimation procedures.

The NSSS results, particularly those indicating that concentrations of metals in biosolids were lower than estimated by the "40 Cities Study," were used in important ways to revise the final Part 503 rule. For example, the results provided a basis for (1) excluding organic pollutants from the final Part 503 rule, (2) developing low pollutant concentration limits for minimally regulated biosolids, and (3) establishing 99th-percentile ceiling concentration limits, as discussed later in this chapter.

Table 4

Peer Review Committee Recommendations Concerning the Part 503 Proposed Rule Risk Assessment (USDA/CSRS, 1989)

The Peer Review Committee (PRC) recommended that EPA revise and repropose the Part 503 rule after revision and correction of the risk assessment methodology. The recommended revisions included more realistic most exposed individuals (MEIs) and models, inclusion of "clean" biosolids, site-specific considerations, and careful selection and use of relevant data. The PRC recommended specifically that EPA should:

- Enlist working groups consisting of experts in biosolids, risk assessment, and modeling to help review the data, revise the scenarios and models, and obtain more realistic pollutant limits.
- Use risk assessment procedures that lead to best estimates and uncertainty bounds rather than calculating upper bound estimates. At a minimum, the MEI should be replaced with an approach that considers exposure situations that are reasonable and that may exist in the United States.
- Use biokinetic models to obtain realistic estimates of absorption, translocation, and excretion of pollutants.
- Use realistic dietary scenarios in calculating food-chain inputs of pollutants in biosolids to humans.
- Use sensitivity analysis to identify the most critical parameters in risk/exposure computations and make efforts to obtain reliable and realistic estimates for these parameters.
- Adhere to normal scientific practices in the use of the number of significant figures when making calculations.
- Use results of field studies involving additions of biosolids rather than results of green house or pot studies involving additions of metal salts or pure organic compounds.
- Use field data to establish Lowest Observed Adverse Effect Levels (LOAELs) or No Observed Adverse Effect Levels (NOAELs) as a basis for calculating pollutant limits.
- Expand the proposed rule to include consideration of potential iron and fluoride toxicity.
- Develop the concept of a "clean" biosolids that allows for minimal regulation.
- Avoid regulating all distributed and marketed (D&M) products as biosolids.
- Require labeling of D&M products to provide consumer information on proper use of the products.
- Drop the MEI scenario for D&M products, a concept that assumes a rural nonfarm family grows 60 percent of their fruit and vegetables in a D&M biosolids-amended home garden for a 70-year lifetime.
- Prepare and address different categories for non-agricultural and D&M practices.
- Exempt from the rule compounds banned from use in the United States that have been shown to pose insignificant risk (e.g., lindane, chlordane, PCBs, hexachlorobutadiene). This action would be consistent with the screening approach used by EPA (i.e., Environmental Profile and Hazard Indices) to eliminate low priority pollutants from consideration.
- Develop more realistic data bases, assumptions, and risk exposure models consistent with results from field studies using biosolids-applied PCB, and perform detailed reevaluation and analyses of the PCB pathways.
- Use two distinct frameworks to assess risk for non-agricultural land:
  - Exposure and significant future conversion very low
  - Exposure more likely or conversion more probable
- Allow for exception to the 5-year conversion period in non-agricultural land application on a case-by-case basis.
- Drop 98th-percentile approach.

Table 4 (Continued)

- Continue the approach of separating the vector attraction reduction requirements from the pathogen reduction requirements in the proposed regulation.
- Regulate pathogens on a risk-based approach. In the interim, the existing requirements in 40 CFR 257 should be maintained.
- Replace the air dispersion model with a more realistic model, such as that used for the EPA solid waste incineration program.
- Adopt a consistent approach for including volatile compounds (e.g., benzene and trichloroethylene) in models used to predict air and ground-water transport.
- Exclude from the rule chemicals that the Agency assumes to be lost from biosolids during processing and that are not present in the biosolids in significant amounts.
- Discontinue use of the CHAIN model in SLAPMAN and SLUDGEMAN to model contaminant transport in the unsaturated zone and replace with a more appropriate model, such as PRZM, RUSTIC, or LEACHM.
- Convert output from the unsaturated zone transport model to input for the AT123D saturated zone transport model in such a manner that satisfies conservation of mass.
- Use realistic, site-specific geologic, hydraulic, and chemical parameters as inputs to computer simulations of contaminant transport.
- Differentiate between trench and area monofills because of the different potential for leaching from these types of monofills.
- Modify the proposed definition of surface disposal to reflect the operational difference between storage with no intent for further management and storage as an essential component in an overall biosolids management scheme.
- Avoid requiring methane monitoring at surface disposal sites where biosolids are applied at high rates to the soil surface.
- Establish acceptable analytical methodologies and limits of detection for regulated biosolids pollutants.
- Define the limit of detection (LOD) as the lowest concentration that can be determined to be significantly different from a blank for an analytical test method and sample matrix.
- Replace the sum of individual limits of detection for multiple pollutant categories (e.g., PCBs) with the highest level of detection for any individual parameter in the multiple parameter set.
- Develop a consistent method to use data that are reported as less than the limit of detection.
- Consider a POTW reporting a limit of detection less than or equal to the acceptable limit of detection to be in compliance with any EPA concentration-based pollutant limit derived from that limit of detection.
- Allow the use of zero concentrations from biosolids pollutant data below the limit of detection for laboratories meeting the Agency's analytical standards.

Proposed Changes to the Part 503 Rule:

Some of the changes listed in the *Federal Register* notice were:

- ***Domestic Septage:*** A less complex and more easily implementable regulatory approach that would remain protective of public health and the environment.
- ***Organic Emissions From Biosolids Incinerators:*** An operational (i.e., technology-based) standard rather than risk-based limits.

Table 5

Science Advisory Board Recommendations Concerning the Part 503 Regulatory Approach for Incineration of Biosolids (U.S. EPA, 1989a)

Based on its review of the proposed Part 503 rule's approach for regulating incineration of biosolids, the Science Advisory Board (SAB) recommended:

- EPA has the scientific basis for developing enforceable operational standards (rather than risk-based standards) for organic pollutants that would provide incentives for improving incineration technology and pollution control equipment. Risk-based standards are not recommended because of the wide range of uncertainties in the risk analysis used for biosolids incineration.
- EPA should undertake and support epidemiological research to determine the incidence of adverse health effects in populations residing near existing incineration facilities.

Further, the SAB commended EPA's Office of Water in attempting to develop a risk-based regulation for sewage sludge incinerators. Based on its review of the proposed Part 503 rule's approach to regulating incineration of biosolids, however, the SAB identified several uncertainties associated with the risk analysis that precluded risk-based regulation, including:

- Numerous safety factors were used in the analysis. While each individual factor appears reasonable, the multiplicative use of a series of such factors made the final number unreasonable.
- The methodology did not explicitly assign a measure of uncertainty or confidence to the calculations, but rather a single risk number was used.
- Use of total hydrocarbons (THCs) as a direct indicator of risk is not possible due to the uncertainties associated with field implementation of hot flame-ionization detector (FID) systems and the lack of a direct link between THCs, as measured by FID, and the total spectrum of organics that might be emitted from sewage sludge incinerators. In addition, it has not been demonstrated that hot FID systems can operate continuously in the stack gas environment of sewage sludge incinerators. Thus, it is not appropriate to propose regulations that will demand such operation for compliance.
- THC measurements may at best indicate the combined performance of combustion and air quality control devices, but how these measured concentrations at the stack relate to environmental concentrations of carcinogens remains unknown.

- ***Non-agricultural Land Application of Biosolids:*** Use of exposure pathway analyses rather than a 98th-percentile approach to establish numerical pollutant limits for all non-agricultural land application practices, including forest and range lands, soil reclamation sites, and public contact sites (e.g., parks, golf courses).
- ***Surface Disposal of Biosolids:*** Use of a risk-based exposure assessment approach, similar to the one used for monofills in the proposed rule, rather than a 98th-percentile approach.
- ***Agricultural Land Application of Biosolids:*** Numerous revisions were considered regarding selection of appropriate target organisms, exposure pathways, transport models, and data, including use of:
  - More realistic assumptions that would protect an HEI rather than an MEI for each pathway.
  - New models for aquatic pathways.
  - More plausible dietary data.
  - Updated and more relevant plant uptake and phytotoxicity data from field studies of biosolids-amended soils.
  - "No effect" and non-detection data to establish pollutant limits based on No Observed Adverse Effect Levels (NOAELs) or Lowest Observed Ad-

verse Effect Levels (LOAELs) where appropriate, based on results from numerous studies on phytotoxicity and bioavailability.

- New calculations for the fraction of food derived from biosolids-amended soils.
- Field measurements for the consumption of biosolids or soils by grazing livestock.
- Revised rate of soil consumption by children.

- ***50 Metric Tonnes per Hectare Limit:*** Proposed dropping of the requirement to limit the land application rate to 50 metric tonnes per hectare (mt/ha) in the proposed rule because the use of newer models allowed higher than 50 mt/ha application rates to be calculated in the risk assessments.
- ***Combining Land Application Pollutant Limits:*** Use of only one set of pollutant limits for biosolids that were distributed and marketed or applied to agricultural or non-agricultural land.
- ***Use of the Most Limiting Pathway To Set Pollutant Limits:*** Selection of the most limiting exposure pathway to set the limit for each pollutant.

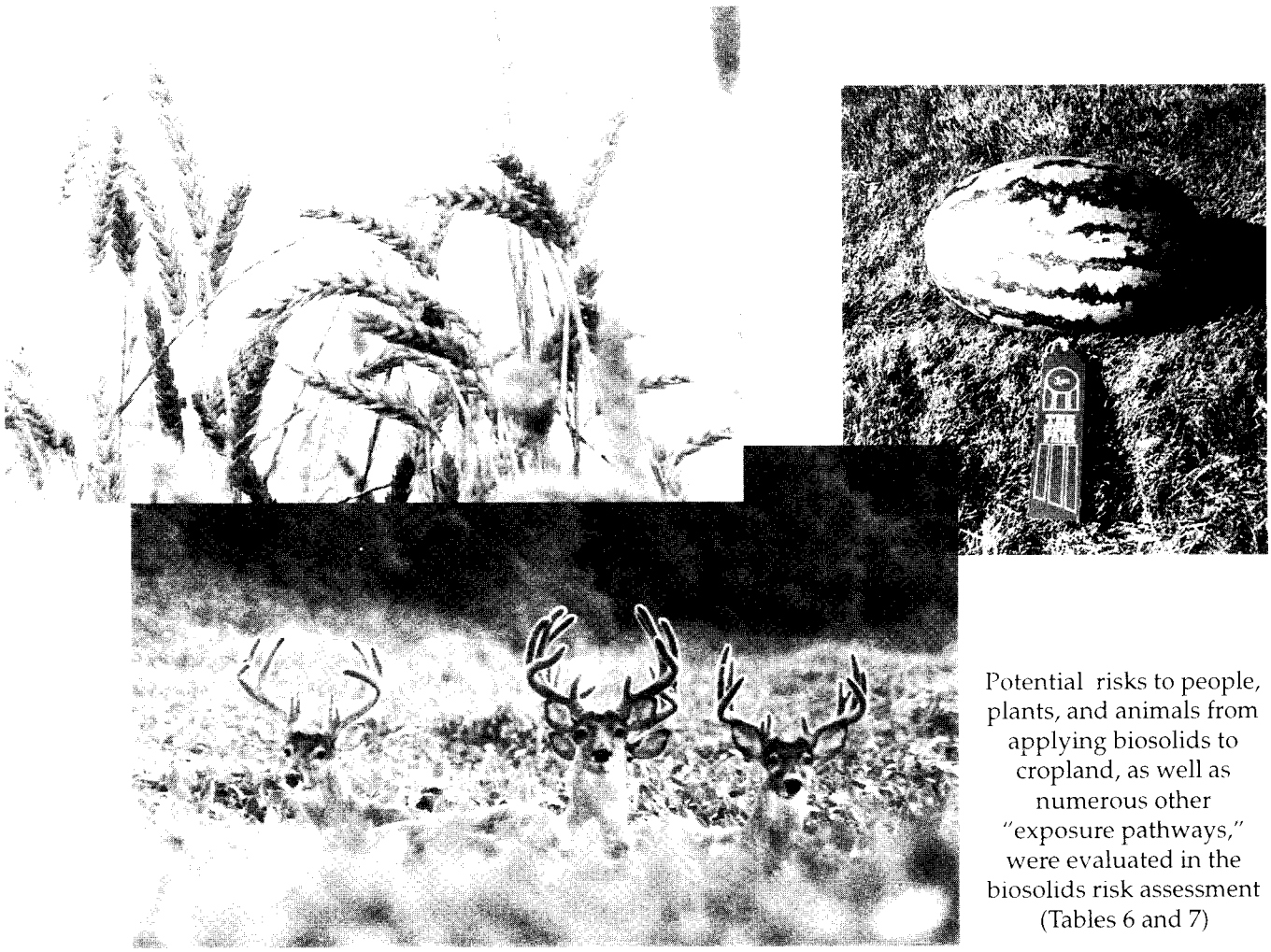
Step M Revised Risk Assessments Conducted for the Final Part 503 Rule

In response to the extensive public and scientific peer review comments received on the proposed rule and the information obtained from the NSSS, EPA (working closely with internationally recognized experts) revised some of the data, models, and assumptions used in the risk assessments for biosolids. Some of the key revisions, summarized in Table 1 and discussed in more detail in Chapter 3, included:

- ***Reassessment of Who Is at Risk:*** EPA used the highly exposed individual (HEI) instead of the most exposed individual (MEI) as the target organism in the revised risk assessment because use of the MEI was criticized as being too conservative, reflecting highly unlikely or unusual circumstances rather than realistic exposure conditions. The HEI reflects more reasonable risks to exposed individuals, while remaining a conservative measure (Habicht, 1992).
- ***Revised Health and Environmental Criteria:*** EPA reviewed and revised its use of health and environmental criteria. As a result, the Agency used a new model for risks associated with lead exposure; developed refined ecological criteria; and used Recommended Daily Allowances (RDAs) when RfDs/RfCs were unavailable.
- ***Reconsideration of Risk Levels:*** EPA reassessed the cancer risk levels of 1×10^{-5} for incineration and 1×10^{-4} for all other use or disposal practices based on new information obtained after the initial risk assessment was conducted. This reassessment indicated minimal risk from all current biosolids use or disposal practices, including incineration. The reassessment resulted in the EPA policy decision to regulate cancer risks for all biosolids use or disposal practices at 1×10^{-4} in the final Part 503 rule.
- ***Revision and Reevaluation of Exposure Pathways,*** including:
  - ***Replacement of the 98th-percentile approach with formal exposure pathway assessments*** for all non-agricultural land application and surface disposal practices, based on new data and modeling techniques. The number of exposure pathways evaluated for non-agricultural land application (e.g., forest lands, soil reclamation sites, and public contact sites) was increased.
  - ***Use of the most stringent of the pollutant limits for each pollutant from all pathways of exposure for land application*** based on revised

risk assessments that predicted similar pollutant limits for agricultural and non-agricultural land application and distribution and marketing.

- ***Use of one risk assessment for all biosolids surface disposal practices,*** including biosolids-only landfilling (monofilling), permanent lagooning, dedicated high-rate surface application for disposal, and dedicated beneficial use. Although there was one risk assessment, two exposure routes were evaluated and the more stringent of the two pollutant limits was chosen as the Part 503 pollutant limit.
- ***Revision of the exposure pathways for ground water, surface water, and air*** in the land application and surface disposal risk assessments to incorporate better fate and transport models and assumptions and to correct techniques used to calculate how much of a pollutant is lost to ground water, surface water, and air. The risk assessments for the proposed rule had used the assumption that 100 percent of any evaluated pollutant could be simultaneously transferred to ground water, surface water, and air. This overly conservative approach was changed. The revised risk assessments used a "mass balance" approach, which more realistically assessed the portion of the pollutant that is transferred to ground water, surface water, and air.
- The exposure pathways used in the revised risk assessments for biosolids are shown in Tables 6 and 7.



Potential risks to people, plants, and animals from applying biosolids to cropland, as well as numerous other "exposure pathways," were evaluated in the biosolids risk assessment (Tables 6 and 7)

Table 6

Summary of Exposure Pathways Used in Risk Assessment for Land Application of Biosolids

Pathway	Description of HEI[a]
1. Biosolids → Soil → Plant → Human	Human (except home gardener) lifetime ingestion of plants grown in biosolids-amended soil
2. Biosolids → Soil → Plant → Human	Human (home gardener) lifetime ingestion of plants grown in biosolids-amended soil
3. Biosolids → Human	Human (child) ingesting biosolids
4. Biosolids → Soil → Plant → Animal → Human	Human lifetime ingestion of animal products (animals raised on forage grown on biosolids-amended soil)
5. Biosolids → Soil → Animal → Human	Human lifetime ingestion of animal products (animals ingest biosolids directly)
6. Biosolids → Soil → Plant → Animal	Animal lifetime ingestion of plants grown on biosolids-amended soil
7. Biosolids → Soil → Animal	Animal lifetime ingestion of biosolids
8. Biosolids → Soil → Plant	Plant toxicity due to taking up biosolids pollutants when grown in biosolids-amended soils
9. Biosolids → Soil → Soil → Organism	Soil organism ingesting biosolids/soil mixture
10. Biosolids → Soil → Soil → Organism → Soil → Organism → Predator	Predator of soil organisms that have been exposed to biosolids-amended soils
11. Biosolids → Soil → Airborne Dust → Human	Adult human lifetime inhalation of particles (dust) (e.g., tractor driver tilling a field)
12. Biosolids → Soil → Surface Water → Human	Human lifetime drinking surface water and ingesting fish containing pollutants in biosolids
13. Biosolids → Soil → Air → Human	Human lifetime inhalation of pollutants in biosolids that volatilized to air
14. Biosolids → Soil → Ground Water → Human	Human lifetime drinking well water containing pollutants from biosolids that leached from soil to ground water

[a] HEI = highly exposed individual

Table 7

Summary of Exposure Pathways Used in Risk Assessments for Surface Disposal and Incineration of Biosolids

Surface Disposal	
Pathway	Description of HEI[a] Exposure for a 70-Year Lifetime
1. Biosolids → Soil → Air → Human	Adult human breathing volatile pollutants from biosolids disposed at a surface disposal site
2. Biosolids → Soil → Ground Water → Human	Adult human drinking water obtained from ground water beneath a surface disposal site
Incineration	
1. Biosolids → Incineration → Particulate → Air → Human	Adult human breathing pollutants in the emissions from a biosolids incinerator

[a]HEI = higly exposed individual

- ***Deletion of Organic Pollutants:*** Based on comments received on the proposed Part 503 rule, EPA reevaluated the organic pollutants regulated by the proposed rule to determine whether any should be deleted from the final regulation. This reevaluation resulted in EPA's policy decision to delete all organic pollutants from land application and surface disposal sections of the final Part 503 rule because these pollutants met one of the following criteria: (1) the pollutant has been banned or restricted for use in the United States or it is no longer manufactured for use in the United States; (2) the pollutant is not present in biosolids at significant frequencies of detection based on data gathered in the NSSS, or (3) the limit for a pollutant from the biosolids exposure assessment is not expected to be exceeded in biosolids that are used or disposed based on data from the NSSS.
- ***Food Consumption Revisited:*** The methodology and data used to calculate dietary exposure to pollutants in biosolids were reviewed and revised to reflect more realistic values representing average lifetime food consumption.
- ***Greater Reliance on Results of Field Studies:*** Field study data were used in the revised risk assessment whenever available (rather than greenhouse pot or metal salt-addition studies) to determine plant uptake of metals and phytotoxicity. New data provided during the public comment and scientific review period indicated that field studies provide a much more realistic basis on which to set biosolids pollutant limits than pot/salt study data, with limits that are more representative of real-world conditions. These new data showed that plants in the field take up metal pollutants at lower rates than predicted based on greenhouse pot/salt addition studies (see photographs, next page), and that these rates remain low over time.
- ***Revised Evaluation of Biosolids Incineration,*** including:
  - Use of an ***updated model*** of incineration of biosolids to evaluate exposure to metal emissions.
  - Determination that ***site-specific modeling and performance testing*** to calculate air dispersion factors and control efficiencies (required in the final rule) are more appropriate than establishing absolute values for those parameters, as was done in the proposed Part 503 rule.
  - Determination that it was infeasible to establish a risk-based numerical limit for total hydrocarbon (THC) emissions from biosolids incinerators, as was included in the proposed rule. Instead, a technology-based ***operational standard for THC*** was included in the final rule.
- ***A New Aggregate (Population) Risk Assessment:*** The aggregate (population) risk assessment conducted for the final Part 503 rule indicated that current use or disposal practices for biosolids pose minimal risk to public health and the environment.

Many of the revisions summarized above are discussed in more detail in Chapter 3.

Step N EPA Review of Science and Policy Decisions Used in the Biosolids Risk Assessments Prior to Issuance of the Final Part 503 Rule

During the review of the final Part 503 rule, several EPA offices raised a number of issues that needed resolution prior to publication of the final rule. These issues are summarized in Table 8. Many of these issues and EPA's resolution of them are discussed in greater detail in Chapter 3.

Table 8

Questions Raised During Internal EPA Review

Topic	Question	Where Addressed in this Document
Pathogens	How should pathogens (e.g., bacteria, viruses) in biosolids be regulated?	Chapter 5
Phytotoxicity	How should phytotoxicity (adverse effects on plants) be defined?	Chapter 3; Chapter 4, Box 10
Lead risks	What methodology should be used to determine risks from exposure to lead in land-applied biosolids?	Chapter 3
Biosolids binding of pollutants	Does "biosolids binding" (the ability of biosolids to strongly react with pollutants, resulting in less pollutant being taken up by plants) persist over time?	Chapter 3
Soil pH	Should soil pH be regulated?	Chapter 5
Ecological risks	Is the ecological risk assessment adequate?	Chapter 3
Margin of safety	Can a 98th- or 99th-percentile approach used as an additional margin of safety be justified?	Chapters 3 and 5
Incineration monitoring	How should incineration monitoring be regulated?	Chapters 2 and 5
Nitrogen in ground water	How should nitrogen that migrates into ground water from biosolids be regulated?	Chapter 3
"Clean" biosolids	Should special provisions to encourage the production of "clean" biosolids (i.e., biosolids containing low levels of pollutants) be included in the final rule?	Chapters 3 and 5

Step O Publication of the Final Part 503 Rule in the *Federal Register*

The final Part 503 rule was published in the *Federal Register* on February 19, 1993 (58 FR 9248). The rule set limits for pollutants that may be present in biosolids that are land applied, surface disposed, or incinerated, as well as other requirements, including management practices, operational standards (i.e., pathogen and vector attraction reduction requirements for land application and surface disposal; THC emissions testing for incinerators), general requirements, and frequency of monitoring, reporting, and recordkeeping requirements (see also Figure 1 in Chapter 1). In addition to the rule itself, the preamble included informative discussions regarding differences between the proposed and final rule pertaining to public and scientific comments, EPA responses to comments, and final actions taken to revise the proposed rule.

Step P Comments, Lawsuits, and Amendments Regarding the Published Final Part 503 Rule

Comments: EPA received comments on the published final Part 503 rule from 89 respondents in response to a request for comments in the Preamble. The comments raised issues regarding the pollutant limits set for cadmium, selenium, and chromium; the use of "annual pollutant loading rates"; use of a percentage of the Maximum Contaminant Level (MCL) for nitrate-nitrogen allowance; and the need for additional ecological field research (see further discussions in Chapter 3). The comments also questioned the need for pollutant limits for molybdenum and the

requirements for monitoring emissions from biosolids incinerators, as discussed below.

Lawsuits Regarding Pollutant Limits for Molybdenum and Chromium: Several POTWs and industry groups as well as the USDA noted errors in the calculation of the uptake slope for molybdenum that caused an underestimation of allowed biosolids molybdenum applications to farmland. Several organizations sued, referring to the error and stating that the limit would significantly restrict the use of biosolids as fertilizer or impose severe restrictions on molybdenum discharge to POTWs without need or benefit. In addition, several industry groups and POTWs initiated lawsuits in which they contended that the land application pollutant limits set for chromium are overly stringent. In particular, plaintiffs argued that because the limits set for chromium were based on a risk assessment that did not identify a limit that would cause harm to public health or the environment, the limits would be unnecessarily detrimental to their industrial practice. On this basis, plaintiffs contended that the limits should be deleted from the rule.

Lawsuits Regarding Biosolids Incinerator Monitoring: Lawsuits also were filed regarding continuous emission monitoring requirements for measuring total hydrocarbons in emissions from biosolids incinerators. The incineration lawsuits questioned the requirement for continuous monitoring of THC emissions from certain incinerators that already had continuous emission monitoring systems for carbon monoxide (CO) in place, which plaintiffs claimed achieved the same results. In addition, arguments were made that EPA was not allowing sufficient time nor providing adequate instruction for installation, start-up, continuous operation, and calibration of continuous emission monitoring systems for THC.

Part 503 Amendment: In response to the public comments received and lawsuits filed, EPA published an amendment to the rule in the Federal Register on February 25, 1994 (59 FR 9095). The amendment states that the Agency is reconsidering the land application pollutant limits for molybdenum. During the period of reconsideration, only the ceiling concentration limit (Part 503, Table 1) must be met for molybdenum. The other pollutant limits (i.e., cumulative pollutant loading rates [Part 503, Table 2], pollutant concentration limits [Part 503, Table 3], and annual pollutant loading rates [Part 503, Table 4]) for molybdenum have been suspended pending additional study by EPA.

In addition, the February 25, 1994, amendment allows continuous CO monitoring to be used as a surrogate for THC monitoring for incinerators that do not exceed 100 ppm_v (parts per million, volume basis) of CO in the exhaust gas. Also, operators of biosolids incinerators are not out of compliance if not monitoring for THC or CO until either a permit has been issued or other federal action has been taken (e.g., Federal Register notification).

Step Q Court Remand of Specific Portions of the Rule

The court remanded certain provisions of the rule to EPA for modification or further justification as a basis for their continued inclusion in the Part 503 rule. These provisions continue to be in effect pending the Agency's review of the remanded portions of the rule.

The remanded portions of the rule include:

- The ***chromium*** pollutant limits
- The ***99th-percentile cap*** used as a pollutant concentration limit for selenium
- Pollutant concentration limits for ***heat-dried biosolids*** (currently not included in Part 503)

These issues are discussed in more detail in Chapter 3.